

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION**

**IN RE: AQUEOUS FILM-FORMING
FOAMS PRODUCTS LIABILITY
LITIGATION**

MDL No. 2:18-mn-2873-RMG

This Document relates to:

- *Donnelly v. 3M Co., et al.*, 20-cv-209
 - *Speers v. 3M Co., et al.*, 21-cv-3181
 - *Voelker v. 3M Co., et al.*, 18-cv-3438
-

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO
EXCLUDE OR PARTIALLY EXCLUDE THE OPINIONS AND TESTIMONY OF
DEFENSE EXPERTS M. DROR MICHAELSON, MD, PHD, RAJ SATKUNASIVAM,
MD, MS, FRCSC, JENNIFER B. GORDETSKY, MD, PETER E. CLARK, MD, BRIAN I.
RINI, MD, FASCO, MICHAEL A. PALESE, MD, THOMAS J. GUZZO, MD, MPH,
DAVID BRAUN, MD, MARTIN RONIS, PHD, AND SARAH COHEN, PHD**

Table of Contents

I.	Introduction.....	2
II.	Factual Background	5
III.	Argument	9
A.	Legal Standard	9
B.	Dr. M. Dror Michaelson's Opinions on General and Specific Causation are Inadmissible 11	
1.	Dr. Michaelson's Opinion that [REDACTED] [REDACTED] is Not Based on Reliable Reasoning and/or Methodology and is Therefore Inadmissible.	11
2.	Dr. Michaelson's Specific Causation Opinions that [REDACTED] [REDACTED] is Not the Product of Reliable Reasoning and/or any Identifiable Methodology.	16
3.	Dr. Michaelson's Opinion that [REDACTED] [REDACTED] is Inadmissible Speculation.	19
C.	Dr. Raj Satkunasivam's General Causation Opinion that [REDACTED] [REDACTED] is Unreliable and Inadmissible as He Failed to Follow a Proper Methodological Protocol for His Literature Review.....	20
D.	Dr. David Braun's Opinion that [REDACTED] [REDACTED] is Not Based on Reliable Reasoning and/or Methodology and is Therefore Inadmissible.	23
E.	Dr. Thomas Guzzo's General Causation Opinion that [REDACTED] [REDACTED] is Unreliable and Inadmissible as He Failed to Follow a Proper Methodological Protocol for His Literature Review.	24
F.	Dr. Jennifer Gordetsky's Opinion that [REDACTED] [REDACTED] is Unreliable and Inadmissible.	26
1.	Dr. Gordetsky's PFAS Literature Summary Includes No Methodology and/or Explanation of the Scope of the Literature Reviewed and/or Weight any Such Literature Was or Was Not Given.	26
2.	Dr. Gordetsky's Opinions Should Be Excluded Because She Failed to Use the Requisite Level of Scientific Rigor in Proffering her Opinions.	29
G.	Both Dr. Peter Clark's General and Specific Causation Opinions Should Be Excluded..	30
1.	Dr. Clark's Opinion that [REDACTED] [REDACTED] is Unreliable and Inadmissible.	30

2. Dr. Clark's Specific Causation Opinion that [REDACTED]	
[REDACTED] is Not the Product of Reliable Reasoning	
and/or any Identifiable Methodology.....	31
H. Drs. Brian Rini's and Michael Palese's Opinions that [REDACTED]	
[REDACTED] are Unreliable and Inadmissible.....	33
I. Dr. Martin Ronis' General Causation Opinions Are Unreliable and Inadmissible as He Failed to Follow a Proper Methodological Protocol for His Literature Review.....	34
J. Dr. Sarah Cohen Should Not Be Permitted to Opine that [REDACTED]	
[REDACTED] Because She Conceded that [REDACTED]	
[REDACTED] and Because, by [REDACTED]	
Her Own Admission, [REDACTED].	
38	
IV. Conclusion	40

Table of Authorities

Cases

<i>Atlantic Coast Pipeline, LLC v. 0.07 Acre, More or Less</i> , 396 F. Supp.3d 628 (W.D. Va. 2019).	34
<i>Barber v. United Airlines, Inc.</i> , 17 F. App'x 433 (7th Cir. 2001).....	13
<i>Campbell v. United States</i> , 470 Fed. Appx. 153 (4th Cir. 2012).....	34
<i>Carr v. Deeds</i> , 453 F.3d 593 (4th Cir. 2006).....	34
<i>Daniels-Feasel v. Forest Pharms., Inc.</i> , No. 17-cv-4188, 2021 U.S. Dist. LEXIS 168292 (S.D.N.Y. 2021)	25, 29, 39
<i>Daubert v. Merrell Dow Pharms., Inc.</i> , 509 U.S. 579 (1993)..... <i>passim</i>	
<i>Freeman v. Ruby Tuesday, Inc.</i> , No. 12-2558, 2013 U.S. Dist. LEXIS 113819 (E.D. Pa. 2013)....	9
<i>Hulsey v. HomeTeam Pets Defense LLC</i> , No. 2:10-cv-03265, 2012 WL 2366385 (D.S.C. June 21, 2012)	34
<i>In re Abbott Lab'y's</i> , 22-C-00071, 2025 U.S. Dist. LEXIS 84032 (N.D. Ill. May 2, 2025)....	25, 35
<i>In re Lipitor (Atorvastatin Calcium) Mktg. Sales Practices & Prods. Liab. Litig.</i> , 145 F. Supp. 3d 573 (D.S.C. 2015)	13
<i>In re Lipitor (Atorvastatin Calcium) Mktg.</i> , 150 F. Supp. 3d 644 (D.S.C. 2015)	19
<i>In re Lipitor Atorvastatin Calcium Mktg., Sales Practices, & Prods. Liab. Litig.</i> , 185 F. Supp. 3d 761 (D.S.C. 2016)	13
<i>In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.</i> , 341 F. Supp. 3d 213 (S.D.N.Y. 2018).....	10, 21, 23
<i>In re Nellson Nutraceutical, Inc.</i> , 356 B.R. 364 (Bankr. D. Del. 2006)	22
<i>In re Rezulin Prods. Liab. Litig.</i> , 369 F. Supp. 2d 398 (S.D.N.Y. 2005)	22
<i>Kumho Tire Co. v. Carmichael</i> , 526 U.S. 137 (1999).	9, 10
<i>Magistrini v. One Hour Martinizing Dry Cleaning</i> , 180 F. Supp. 2d 584 (D.N.J. 2002). 10, 11, 23	
<i>Oglesby v. GMC</i> , 190 F.3d 244 (4th Cir. 1999).....	9
<i>Owens v. Bourns, Inc.</i> , 766 F.2d 145 (4th Cir. 1985)	20
<i>Sharpe v. United States</i> , 230 F.R.D. 452 (E.D. Va. 2005).....	20
<i>Shutt v. Bi</i> , No. 3:20-cv-0722, 2021 U.S. Dist. LEXIS 161732 (D.S.C. Aug. 26, 2021)	9
<i>Trevino v. Boston Sci. Corp.</i> , No. 13-cv-1617, 2016 U.S. Dist. LEXIS 65967 (S.D.W.V. May 18, 2016).....	22
<i>Vieira v. Think Tank Logistics, LLC (In re Levesque)</i> , 653 B.R. 127 (Bankr. D.S.C 2023).....	21
<i>Westberry v. Gislaved Gummi AB</i> , 178 F.3d 257 (4th Cir. 1999).....	9, 10, 19

Rules

Fed. R. Civ. P. 26(a)(2).....	9, 34
Federal Rule 702	<i>passim</i>

Pursuant to Case Management Order (“CMO”) No. 26G, Group A, kidney cancer Plaintiffs Brock Donnelly, Clinton Speers, and Kevin Voelker (“Plaintiffs”), by and through Co-Lead Counsel, hereby submit this Memorandum of Law in Support of their Motion to Exclude or Partially Exclude the Opinions and Testimony of M. Dror Michaelson, M.D., Ph.D., who has been proffered as an expert witness by Defendants E. I. du Pont De Nemours and Co., the Chemours Co. FC, L.L.C., and Clariant Corporation (referred to as “DuPont/Chemours” and “Clariant,” respectively);¹ Raj Satkunasivam, M.D., who has been proffered as a witness by Defendants BASF Corporation, Buckeye Fire Equipment Co., Chemguard Inc., Clariant Corporation, and Tyco Fire Products LP (referred to as “BASF,” “Buckeye,” “Chemguard,” “Clariant” and “Tyco,” respectively);² Thomas J. Guzzo,³ M.D., M.P.H., who has been proffered as an expert witness by Telomer Defendants (i.e., AGC Chemicals Americas, Inc. (“AGC”), Amerex Corporation (“Amerex”), Arkema Inc. (“Arkema”), BASF, Buckeye, Chemguard, Clariant, and Tyco); Sarah Cohen, PhD;⁴ who has been proffered as an expert witness by all the aforementioned Telomer Defendants except Amerex; David Braun, M.D.,⁵ who has been proffered as an expert witness by

¹ Dr. Michaelson served three (3) case-specific expert reports, one for each of the three (3) kidney cancer cases, *Donnelly* (“Michaelson – *Donnelly Report*”), *Speers* (“Michaelson – *Speers Report*”) and *Voelker* (“Michaelson – *Voelker Report*”), attached hereto as Exs. 1, 2, and 3, respectively.

² Dr. Satkunasivam served one (1) case-specific expert report in the *Voelker* case only (“Satkunasivam – *Voelker Report*”), attached hereto as Ex. 4.

³ Dr. Guzzo served one (1) case-specific expert report in the *Speers* case only (“Guzzo – *Speers Report*”), attached hereto as Ex. 5.

⁴ Dr. Cohen served one (1) general report in all three (3) cases (“Cohen Report”), attached hereto as Ex. 6.

⁵ For the avoidance of confusion, it is important to bring to the Court’s attention that both sides have retained an expert with the last name “Braun.” Plaintiffs have retained Dr. Joseph Braun while Defendants have retained Dr. David Braun. As such, hereinafter, Dr. Joseph Braun will be referred to as Joseph Braun or J. Braun with Dr. David Braun being referred to as D. Braun.

all the aforementioned Telomer Defendants except Amerex and Arkema,⁶ and Jennifer B. Gordetsky, M.D.,⁷ Peter E. Clark, M.D.,⁸ Michael Palese, M.D.,⁹ Brian Rini, M.D.,¹⁰ and Martin Ronis, PhD,¹¹ who have been proffered as expert witnesses by Defendant 3M Company (referred to as “3M”).

I. INTRODUCTION

Defendants proffer ten (10) experts to opine [REDACTED]

[REDACTED]. Although each expert reaches similar conclusions, the way they reached their conclusions renders their opinions unreliable under *Daubert* and the Federal Rules of Evidence.¹² One precept of evaluating a proper methodology under *Daubert* is the ability to test or verify that the methodology by which the expert’s findings were reached was reliably conducted.¹³ As discussed below, these experts’ unstructured scientific literature review, whose methodology (if any) is never explained, renders

⁶ Dr. D. Braun served one (1) case-specific expert report in the *Donnelly* case only (“D. Braun - *Donnelly* Report”), attached hereto as Ex. 7.

⁷ Dr. Gordetsky also served case-specific expert reports for all three (3) kidney cancer Plaintiffs, attached hereto as *Voelker* Expert Report (“Gordetsky – *Voelker* Report”), *Donnelly* Expert Report (“Gordetsky – *Donnelly* Report”), and *Speers* Expert Report (“Gordetsky – *Speers* Report”), attached hereto as Exs. 8, 9, and 10.

⁸ Dr. Clark served one (1) case-specific expert report in the *Donnelly* case only (“Clark – *Donnelly* Report”), attached hereto as Ex. 11.

⁹ Dr. Palese served one (1) case-specific expert report in the *Speers* case only (“Palese – *Speers* Report”), attached hereto as Ex. 12.

¹⁰ Dr. Rini served one (1) case-specific expert report in the *Voelker* case only (“Rini – *Voelker* Report”), attached hereto as Ex. 13.

¹¹ Dr. Ronis served one (1) general report in all three (3) cases (“Ronis Report”), attached hereto as Ex. 14.

¹² Notably, Plaintiffs have attempted to be judicious in their *Daubert* motions, only moving against ten (10) of Defendants’ combined fifty-one (51) experts, forty-nine (49) of whom provided expert reports.

¹³ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993).

their general causation opinions unreliable. Moreover, certain of these experts' specific-causation opinions fare no better.

Defendants' expert, Dr. M. Dror Michaelson, purports to proffer a general causation opinion, namely, that [REDACTED]

[REDACTED]"¹⁴ in addition to a specific causation opinion, that, [REDACTED]

[REDACTED]¹⁵ Similarly, Dr. Satkunasivam opines that [REDACTED]

[REDACTED]¹⁶ Dr. D. Braun also opines that [REDACTED]

[REDACTED]¹⁷ Despite these experts attempting to proffer both general and case-specific causation opinions, each fails to adhere to any reliable reasoning and/or methodology to reach such opinions, and, therefore, these opinions fail to meet the strict standards of Federal Rule 702, *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and its progeny. Because Drs. Michaelson, Satkunasivam, and D. Braun

¹⁴ Ex. 3, Michaelson - *Voelker Report*, at 8; *see also*, Ex. 1, Michaelson - *Donnelly Report*, at 8; Ex. 2, Michaelson - *Speers Report*, at 8.

¹⁵ Ex. 3, Michaelson - *Voelker Report*, at 10; *see also*, Ex. 2, Michaelson - *Speers Report*, at 9 (stating his opinion [REDACTED]); Ex. 1, Michaelson - *Donnelly Report*, at 10 (stating his opinion [REDACTED])

¹⁶ Ex. 4, Satkunasivam - *Voelker Report*, at 3.

¹⁷ Ex. 7, D. Braun - *Donnelly Report*, at 1.

failed to employ proper and reliable methodologies and/or reasoning in reaching their opinions outlined above, these opinions are not reliable and thus should be excluded.

Likewise, 3M's experts, Drs. Jennifer Gordetsky, Brian Rini, and Michael Palese, purport to proffer general causation opinions that [REDACTED]

[REDACTED]. However, they also fail to articulate any sound methodology to reach such opinions, and, therefore, fail to meet the standards of Federal Rule 702 and *Daubert*. The absence of any reliable methodology is underscored by Drs. Gordetsky's, Rini's, and Palese's patent failure to utilize the same level of scientific rigor in this case that they use in their respective disciplines. Because Dr. Gordetsky failed to employ a proper and reliable methodology in her practice as a urologic pathologist in reaching the opinions outlined above, her opinions are not reliable and should be excluded. So too for Drs. Rini and Palese.

Dr. Peter Clark also proffers an opinion in Mr. Donnelly's case that [REDACTED]

[REDACTED]¹⁸ However, Dr. Clark, just as with each expert identified above, fails to identify any methodology as to how he reached this opinion besides a basic review of medical literature. As discussed below, a simple review of medical literature without applying a systematic methodology does not meet the standards of Federal Rule of Evidence 702 and *Daubert*.

Similarly, Dr. Thomas Guzzo proffers an opinion that, [REDACTED]

[REDACTED]. Dr. Guzzo's methodology, to the extent he has one, is unreliable, as with each expert

¹⁸ Ex. 11, Clark – *Donnelly* Report, at 13.

identified above, because it is not fully explained nor was it a proper systematic review of the relevant literature.

Dr. Martin Ronis proffers an opinion that [REDACTED]

[REDACTED]. However, Dr. Ronis' opinion suffers from the same lack of methodology as Defendants' other experts as he offers no explanation as to his methodology besides that he conducted unidentified searches on PubMed. Dr. Ronis' opinions [REDACTED] [REDACTED], should also be excluded for the additional reason that he failed to provide a coherent rationale for [REDACTED]
[REDACTED].

Lastly, because Dr. Sarah Cohen [REDACTED]
[REDACTED]
[REDACTED], and because she failed to consider evidence directly relevant to her opinions, her opinions too should be excluded.

II. FACTUAL BACKGROUND

Plaintiffs claim that their drinking water supplies, which include the Ambler Borough Water Department (ABWD), Horsham Water and Sewer Authority (HWSA), and Warminster Municipal Authority (WMA), were contaminated with AFFF as a result of the use of AFFF at the Naval Air Station Joint Reserve Willow Grove (NASJRB) and the Naval Air Warfare Center Warminster (NAWC).¹⁹ As Plaintiffs' exposure assessment expert, Dr. David MacIntosh, opines,

¹⁹ Expert Report of David L. MacIntosh, ScD, CIH, DABT ("MacIntosh Report"), dated Feb. 15, 2025, at 12-14, attached as Ex. 15; *see also*, Penn. PFAS Multi-Site Study ("MSS"), "PA PFAS Health Study Update," available at:

https://papfas.rti.org/PA_PFAS_MSS_Newsletter_March_2024.pdf (stating that ABWD, HWSA, and WMA are amongst the Townships within Bucks and Montgomery Counties in Pennsylvania that have been selected by the ATSDR for study (along with other such sites across the country) because of drinking water contamination as a result of AFFF use.)

[REDACTED]

[REDACTED]

[REDACTED]

²⁰ In fact, given

this high-level of AFFF contamination, preliminary results from the MSS, a study reporting on PFAS and health outcomes in the area that includes the Townships of Ambler, Horsham, and Warminster, reported that members of this community have PFOA, PFOS, and PFHxS levels that, on average, “exceed what would be expected in about 95% of the United States adult population.”²¹

AFFF contains the chemicals PFOS, PFOA, and PFOA precursors, which have been recognized by multiple health authorities around the world, including the United States Environmental Protection Agency (“EPA”), as being carcinogenic and for which, not unlike carcinogens more generally, there is no threshold dose.²² For *decades* prior to their diagnoses of cancer, each of the Plaintiffs had been unknowingly exposed to these toxic chemicals in their drinking water. In assessing each Plaintiffs’ PFAS exposure, Dr. MacIntosh opines that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] For Messrs. Voelker and Speers, he further opines that [REDACTED]

[REDACTED]

²⁰ Ex. 15, MacIntosh Report, at 7, Summary Opinions Nos. 1-2.

²¹ MSS, Initial Summary PFAS Results, *available at*: <https://papfas.rti.org/>.

²² 88 Fed. Reg. 18638 (Mar. 29, 2023), at 18639, *available at*: <https://www.govinfo.gov/content/pkg/FR-2023-03-29/pdf/2023-05471.pdf> (stating that, “[f]ollowing a systematic review of available human epidemiological and animal toxicity studies, EPA has determined that PFOA and PFOS are *likely to cause cancer* (e.g., kidney and liver cancer) and that there is *no dose below which either chemical is considered safe...*”) (emphasis added).

[REDACTED].²³ With respect to Mr. Donnelly, [REDACTED]

[REDACTED]²⁴ Given their widespread presence in the environment, and given that these are carcinogens for which there is no known safe or threshold dose, the National Academy of Science Engineering and Medicine (“NASEM”) have provided clinicians with reasonable guidelines to monitor and/or screen patients for potential health effects who have had PFAS exposure, including PFOA and PFOS, noting that for serum PFAS levels between 2 and 20 ng/ml, “[t]here is a potential for adverse effects,” and above 20 ng/mL, “[t]here is an increased risk of adverse effects.”²⁵

Plaintiffs’ general causation expert opines that [REDACTED]

[REDACTED].^{26, 27} As noted herein, that opinion

²³ Ex. 15, MacIntosh Report, at 8, Summary Opinions Nos. 5, 6, and 9.

²⁴ Ex. 15, MacIntosh Report, at 8, Summary Opinion No. 9.

²⁵ National Academies Sciences Engineering Medicine (“NASEM”), Guidance on PFAS Exposure, Testing, and Clinical Follow-Up (2022) (“NASEM Guidance”), at Recommendation 5-3, at 11, available at: <https://nap.nationalacademies.org/download/26156#>. It is worth noting that NASEM’s Clinical Guidelines combine six (6) different PFAS, including PFOA, PFOS, and PFHxS, in calculating a NASEM “score” for the purposes of the clinical guidelines.

²⁶ Expert Report pf Joseph M. Braun, RN, MSPH, PhD (“J. Braun Report”), dated Feb. 14, 2025, at 1, 62, 65, attached as Ex. 16 (opining [REDACTED]).

²⁷ As carcinogens, there is no safe level of exposure to either PFOA or PFOS. See Dep. Tr. of David MacIntosh, ScD, CIH, DABT, dated May 22, 2025, at 246:2-16, relevant portions attached as Ex. 17 (testifying that [REDACTED]); see also, Dep. Tr. of David H. Sherman, PhD, dated May 13, 2025, at 101:7-103:21, relevant portions attached as Ex. 18 (explaining that [REDACTED]).

[REDACTED]; 88 Fed. Reg. 18638 (Mar. 29, 2023), at 18639, available at: <https://www.govinfo.gov/content/pkg/FR-2023-03-29/pdf/2023-05471.pdf> (stating that “[f]ollowing a systematic review of available human epidemiological and animal toxicity studies, EPA has determined that PFOA and PFOS are *likely to cause cancer* (e.g., kidney and liver cancer) and that there is *no dose below which either chemical is considered safe...*”)(emphasis added).

is consistent with the conclusions of major health agencies, including EPA. In reaching his specific-causation opinions, Plaintiffs' expert considered this in addition to, among other things, Plaintiffs' significant PFAS exposure, EPA's April 2024 classification of PFOA and PFOS as Likely to Be Carcinogenic to Humans,²⁸ the International Agency for Research on Cancer's ("IARC") classification of PFOA as carcinogenic to humans (Group 1) and PFOS as possibly carcinogenic to humans (Group 2B),²⁹ and NASEM's finding that there was "sufficient evidence of increased risk...with exposure to PFAS"³⁰ and kidney cancer in adults. Then, after applying the well-established differential etiology methodology, Plaintiffs' specific causation expert [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].³¹

Against this overwhelming evidentiary backdrop, several of Defendants' experts purport to provide the opinion that [REDACTED]. However, as discussed below, none of these experts provide a reliable foundation for these outlier general causation opinions, on which they also then rely to proffer their case-specific causation opinions, and thus should be precluded from proffering their unreliable opinions.

²⁸ EPA Apr. 2024, Maximum Contaminant Level Goals for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water ("EPA MCLG"), at §§ 3.1.2.1, 3.2.2.1, available at: https://www.epa.gov/system/files/documents/2024-04/mclg-doc-for-pfoa-pfos_final-508.pdf.

²⁹ IARC Monographs, Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) ("2025 IARC Monograph"), at 717, §6.4, available at: <https://publications.iarc.who.int/636>.

³⁰ NASEM Guidance, at 143-144, available at: <https://nap.nationalacademies.org/download/26156#>.

³¹ Expert Reports of Robert Bahnson, MD, FACS, dated February 18, 2025, for Plaintiffs Donnelly, Voelker and Speers ("Bahnson – Donnelly Report, Bahnson – Voelker Report, and Bahnson – Speers Report), at 3-4, 4, and 4, attached as Exs. 19, 20, and 21, respectively.

III. ARGUMENT

A. Legal Standard

Rule 26(a)(2) requires that a testifying expert must prepare and sign³² a report, “if the witness is one retained or specially employed to provide expert testimony in the case....” Fed. R. Civ. P. 26(a)(2)(B). In addition, the Rule requires that the expert report contain a complete statement of all opinions the witness will express and the bases for them as well as the facts or data considered by the expert in forming the opinions. Fed. R. Civ. P. 26(a)(2)(B)(i)-(ii).

“Expert testimony is admissible under Rule 702 . . . if it concerns (1) scientific, technical, or other specialized knowledge that (2) will aid the jury or other trier of fact to understand or resolve a fact at issue.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260-61 (4th Cir. 1999) (citing *Daubert*, 509 U.S. at 592). “The purpose of this rule is to ensure ‘the same level of intellectual rigor that characterizes the practice of an expert in the relevant field’ is presented in the courtroom.” *Shutt v. Bi*, No. 3:20-cv-0722, 2021 U.S. Dist. LEXIS 161732, at *3 (D.S.C. Aug. 26, 2021) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

Rule 702 and *Daubert* require that in proffering their opinions, experts utilize a reliable methodology. “A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods.” *Oglesby v. GMC*, 190 F.3d 244, 250 (4th Cir. 1999) (emphasis in original) (citation omitted). Therefore, “the focus of the Court’s inquiry must be on the expert’s methods, not his conclusions.” *Freeman v. Ruby Tuesday, Inc.*, No. 12-2558, 2013 U.S. Dist. LEXIS 113819, at *3-4 (E.D. Pa. 2013).

³² Of note, Dr. Gordetsky’s expert report in *Voelker* (Ex. 8) was served unsigned and thus is also facially deficient.

In personal injury cases, typical methodologies may include a systematic review of the literature to assess epidemiological studies and/or a differential diagnosis in rendering a case specific causation opinion – neither of which were used by Defendants’ experts here. Notably, when relying on scientific literature to form an opinion, an expert must “weight[] the studies he has chosen to include in order to prevent a mere listing of studies and jumping to a conclusion.” *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (D.N.J. 2002). An expert is also required to “rigorously explain how they have weighted the criteria.” *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 341 F. Supp. 3d 213, 247 (S.D.N.Y. 2018). “Otherwise, such methodologies are virtually standardless and their applications to a particular problem can prove unacceptably manipulable.” *Id.*

“The first prong of [the Daubert] inquiry necessitates an examination of whether the reasoning or methodology underlying the expert’s proffered opinion is reliable—that is, whether it is supported by adequate validation to render it trustworthy.” *Westberry v. Gislaved Gummi AB*, 178 F.3d at 260 (citing *Daubert*, 509 U.S. at 590). “The second prong of the inquiry requires an analysis of whether the opinion is relevant to the facts at issue.” *Id.* (citing *Daubert*, 509 U.S. at 591) “Thus, an expert’s testimony is admissible under Rule 702 if it ‘rests on a reliable foundation and is relevant.’” *Id.* (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999)).

As discussed below, none of Defendants’ expert reports identified here meet these standards as they do not identify the methodology relied upon to form their opinions, because they failed to weigh the studies they chose to rely on, and for the additional reasons discussed below. Their opinions are simply conclusions based on a review of cherry-picked literature and are therefore unreliable and do not meet the standards under Rule 702 and *Daubert*.

B. Dr. M. Dror Michaelson's Opinions on General and Specific Causation are Inadmissible

1. Dr. Michaelson's Opinion that [REDACTED]

**[REDACTED]
is Not Based on Reliable Reasoning and/or Methodology and is
Therefore Inadmissible.**

Dr. Michaelson indicates that [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] „³³

Dr. Michaelson should not be permitted to opine that [REDACTED]

[REDACTED] because he failed to identify any well-established methodology to explain how he selected the medical literature that he reviewed in order to come to his conclusion that [REDACTED]. He further failed to explain what weight, if any, any particular piece of epidemiological literature he reviewed was given.³⁴ Because no identifiable methodology was followed for his literature review, but rather literature was seemingly cherry-picked for unexplained reasons without any analysis of the import of each specific piece of literature reviewed, Dr. Michaelson's opinions are not reliable and, therefore, should be excluded.³⁵

³³ Ex. 3, Michaelson - *Voelker* report, at 6, 8; *see also*, Ex. 1, Michaelson - *Donnelly* Report, at 6, 8; Ex. 2, Michaelson - *Speers* Report, at 6, 8.

³⁴ As discussed, *infra*, the only discussion whatsoever of any “literature” by Dr. Michaelson includes [REDACTED]

[REDACTED] and this “discussion” does nothing to elucidate any reliable method and/or reasoning that Dr. Michaelson may have employed to [REDACTED].

³⁵ See, e.g., *Magistrini*, 180 F. Supp. 2d at 602 (“Importantly, because the weight-of-the-evidence methodology involves substantial judgment on the part of the expert, it is crucial that the expert

As Defendants' expert, Dominik Alexander, Ph.D., states in his expert report, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

³⁶

This is echoed by Defendants' expert, Dr. Sarah S. Cohen, who states that [REDACTED]

[REDACTED]
[REDACTED]

[REDACTED] ³⁷ She goes on to agree generally with Dr. Alexander that [REDACTED]:

[REDACTED]
³⁸

During her deposition, Dr. Cohen confirmed that [REDACTED]

[REDACTED]
[REDACTED]

[REDACTED].³⁹ She further confirmed that [REDACTED],⁴⁰ which

supply his method for weighting the studies he has chosen to include in order to prevent a mere listing of studies and jumping to a conclusion.”).

³⁶ Expert Report of Dominik D. Alexander, PhD, MSPH (“Alexander Report”), at 25, attached hereto as Ex. 22.

³⁷ Ex. 6, Cohen Report, at 7.

³⁸ *Id.* at 7-8.

³⁹ Dep. Tr. of Sarah S. Cohen, PhD (“Cohen Dep”), at 180:23-181:4, relevant pages attached as Ex. 23.

⁴⁰ *Id.* at 180:15-19.

underscores the unreliable nature of their reviews and conclusions of the epidemiological literature.

Despite Defendants' experts' acknowledgment that [REDACTED]

[REDACTED], and despite Dr. Michaelson listing various epidemiological studies that he reviewed in Appendix C of each of his three (3) expert reports, Dr. Michaelson nonetheless does not employ a systematic review methodology, he does not identify inclusion or exclusion criteria for the studies he reviews, he does not identify the search criteria that he used to identify the universe of studies that he reviewed, nor does he assess the validity of studies through a bias assessment or interpret the epidemiological studies pursuant to any identified epidemiological protocols.

Rather, his study selection appears to be an unreliable, haphazard cherry-picking of literature, and, perhaps even more troubling, he focuses on, and highlights, snippets of [REDACTED]

[REDACTED] See *In re Lipitor Atorvastatin Calcium Mktg., Sales Practices, & Prods. Liab. Litig.*, 185 F. Supp. 3d 761, 782 (D.S.C. 2016)(stating that “[b]asing an opinion on . . . cherry-picked data is unreliable and does not satisfy *Daubert*.”) (citing *Barber v. United Airlines, Inc.*, 17 F. App’x 433, 437 (7th Cir. 2001)); see also, *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007) (holding that opinions reached by cherry-picking “does not reflect scientific knowledge, is not derived by the scientific method, and is not ‘good science’”); *In re Lipitor (Atorvastatin Calcium) Mktg. Sales Practices & Prods. Liab. Litig.*, 145 F. Supp. 3d 573, 594 (D.S.C. 2015) (holding that “general causation opinions cannot be based on cherry-picked studies.”)

The only discussion of the “medical literature” that Dr. Michaelson reviewed includes a [REDACTED]

[REDACTED]. As it pertains to [REDACTED], Dr. Michaelson appears to suggest that [REDACTED]

[REDACTED]”^{41, 42} That is the full extent of his analysis of this piece of medical literature. [REDACTED] EPA’s ultimate April 2024 conclusion that both PFOA and PFOS are considered by EPA as “*Likely to Be Carcinogenic to Humans.*”⁴³ [REDACTED],

clearly qualifies as cherry-picking and thus is not derived from a proper scientific method.

Beyond EPA’s 2024 toxicity assessment, [REDACTED]

[REDACTED].⁴⁴ Of course, this

⁴¹ Ex. 3, Michaelson - *Voelker Report*, at 6; *see also*, Ex. 1, Michaelson - *Donnelly Report*, at 6; Ex. 2, Michaelson - *Speers Report*, at 6.

⁴² Ironically, with respect to occupational studies involving PFAS, another of Defendants’ experts, Dr. Satkunasivam, [REDACTED]:

[REDACTED]

Ex. 4, Satkunasivam – *Voelker Report*, at 12; *see also*, Ex. 6, Cohen Report, at 53 (noting that [REDACTED])

⁴³ EPA MCLG, at §§ 3.1.2.1; 3.2.2.1, available at: https://www.epa.gov/system/files/documents/2024-04/mclg-doc-for-pfoa-pfos_final-508.pdf; *see also*, April 2024, FINAL Human Health Toxicity Assessment for Perfluorooctanoic Acid (PFOA) and Related Salts (“EPA Final PFOA Toxicity Assessment”), at 3-343, available at: <http://epa.gov/system/files/documents/2024-05/final-human-health-toxicity-assessment-pfoa.pdf>.

⁴⁴ Ex. 3, Michaelson - *Voelker Report*, at 6.

entirely buries the lead as it pertains to PFOA, which IARC classified as a Group 1 carcinogen, meaning that it finds PFOA to be carcinogenic to humans.⁴⁵ Group 1 is IARC's highest possible level of classification, and while this classification includes consideration of mechanistic and animal data in addition to human data, [REDACTED]

[REDACTED]
[REDACTED].

Dr. Michaelson also provides no analysis whatsoever of any of the observational epidemiological studies that he reviewed, concluding only that [REDACTED]

[REDACTED]"⁴⁶ Of course that is of no moment because, in addition to rendering a specific causation opinion, Dr. Michaelson purports to offer an opinion [REDACTED]

[REDACTED].⁴⁷ Despite this, he offers zero analysis of any of these epidemiological studies, yet, nonetheless incorporates [REDACTED] in rendering his general causation opinion without any analysis of the import of these studies. Such analysis is critical and necessary under any purported weight of the evidence analysis. In short, simply [REDACTED]' does not render an otherwise inadequate methodology, suddenly adequate, where an expert utterly fails to weigh any of the studies cited in his/her report.

⁴⁵ 2025 IARC Monograph, at 717, available at: <https://publications.iarc.who.int/636>.

⁴⁶ Ex. 3, Michaelson - Voelker, at 6; see also, Ex. 1, Michaelson - Donnelly Report, at 6; Ex. 2, Michaelson - Speers Report, at 6.

⁴⁷ Ex. 6, Cohen Report, at 5 (stating that [REDACTED]

Finally, Dr. Michaelson also fails to acknowledge that in 2022, a [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]"⁴⁸ Given that Dr. Michaelson proffers an outlier opinion about [REDACTED] that is inconsistent with EPA, IARC, and NASEM, it is even more important that he "show his work" when rendering the opinion that [REDACTED]

Because Dr. Michaelson both cherry-picks portions of medical literature to rely on, while often leaving out entire conclusions in order to arrive at the opinion that [REDACTED]
[REDACTED], and likewise fails to provide any method by which he selected and/or weighed the value of the medical literature he reviewed, including, for example, considering potential bias and/or the presence of confounding factors, or any discussion whatsoever of the epidemiology, his opinions are not the result of a reliable method and/or reasoning and thus should be excluded.

2. Dr. Michaelson's Specific Causation Opinions that [REDACTED]

[REDACTED] is Not the Product of Reliable Reasoning and/or any Identifiable Methodology.

Dr. Michaelson offers affirmative case-specific causation opinions that [REDACTED]

[REDACTED]

[REDACTED] However, Dr. Michaelson fails to identify any methodology and/or reliable reasoning that he followed to arrive at these specific causation opinions, thereby rendering his opinions unreliable and inadmissible.

⁴⁸ Ex. 8, Gordetsky - Voelker Report, at 25; see also, Ex. 9, Gordetsky - Donnelly Report, at 25; and Ex. 10, Gordetsky - Speers Report, at 25. See also NASEM Guidance, at 143-144, available at: <https://nap.nationalacademies.org/download/26156#>.

As set forth below, no less than six (6) separate times in his 10-page report, Dr. Michaelson opines that [REDACTED]:

- [REDACTED]⁴⁹
- [REDACTED]⁵⁰
- [REDACTED]⁵¹
- [REDACTED]⁵²
- [REDACTED]⁵³ and
- [REDACTED]⁵⁴

Despite these half dozen pronouncements, not one of these sentences are followed by a citation, but nonetheless appear to be the only basis for his opinions [REDACTED]

⁴⁹ Ex. 3, Michaelson - *Voelker Report*, at 3; *see also*, Ex. 2, Michaelson - *Speers Report*, at 3; Ex. 1, Michaelson - *Donnelly Report*, at 3.

⁵⁰ Ex. 3, Michaelson - *Voelker Report*, at 3; *see also*, Ex. 2, Michaelson - *Speers Report*, at 3; Ex. 1, Michaelson - *Donnelly Report*, at 3.

⁵¹ Michaelson - *Voelker Report*, at 4; *see also*, Ex. 2, Michaelson - *Speers Report*, at 4; Ex. 1, Michaelson - *Donnelly Report*, at 4.

⁵² Ex. 3, Michaelson - *Voelker Report*, at 5; *see also*, Ex. 2, Michaelson - *Speers Report*, at 5; Ex. 1, Michaelson - *Donnelly Report*, at 5.

⁵³ Ex. 3, Michaelson - *Voelker Report*, at 9; *see also*, Ex. 2, Michaelson - *Speers Report*, at 8; Ex. 1, Michaelson - *Donnelly Report*, at 9.

⁵⁴ Ex. 3, Michaelson - *Voelker Report*, at 10; *see also*, Ex. 2, Michaelson - *Speers Report*, at 9; Ex. 1, Michaelson - *Donnelly Report*, at 10.

[REDACTED]. Just repeating the same pronouncement over and over, however, does not make the conclusion the product of a reliable method. Rather, to pass *Daubert* muster, Dr. Michaelson's specific causation opinions must be based on reliable reasoning and/or methodology, which they are not. In fact, no methodology is identified at all other than [REDACTED]

[REDACTED]

[REDACTED] ⁵⁵ However, simply parroting the relevant buzz words does not satisfy *Daubert*. Moreover, Dr. Michaelson's lack of scientific rigor in forming his opinions is underscored by his apparent lack of any understanding of the materials he reviewed.

Specifically, despite claiming to [REDACTED], Dr. Michaelson inaccurately states that [REDACTED]

[REDACTED]"⁵⁶ He then concludes that [REDACTED]

[REDACTED]

[REDACTED]"⁵⁷ These statements are patently incorrect. In his expert report, Dr. Bahnsen [REDACTED]

[REDACTED]

[REDACTED]. Furthermore, even assuming TCE was associated with environmental exposure, he understood, [REDACTED], that

⁵⁵ Ex. 3, Michaelson - *Voelker* Report, at 3; *see also*, Ex. 2, Michaelson - *Speers* Report, at 3; Ex. 1, Michaelson - *Donnelly* Report, at 3.

⁵⁶ Ex. 3, Michaelson - *Voelker* Report, at 9; *see also*, Ex. 1, Michaelson - *Donnelly* Report, at 9 (claiming incorrectly that Dr. Bahnsen failed to perform an exposure analysis related to Mr. Donnelly's exposure to TCE).

⁵⁷ Ex. 3, Michaelson - *Voelker* Report, at 9; *see also*, Ex. 1, Michaelson - *Donnelly* Report, at 9 (claiming inaccurately that because Dr. Bahnsen did not consider TCE, he cannot rule it out as a cause of Mr. Donnelly's kidney cancer).

This misunderstanding of the factual record underscores Dr. Michaelson's lack of scientific rigor in proffering his opinions here, and renders this opinion unreliable.

As the proponent of Dr. Michaelson, Defendants bear the burden of proof to establish the admissibility of their expert's opinion testimony and thus, to the extent that their experts choose to proffer affirmative causation opinions as Dr. Michaelson has done here, such opinions must comply with Rule 702 and *Daubert*, including following a reliable methodology.⁵⁸

3. Dr. Michaelson's Opinion that [REDACTED] s Inadmissible Speculation.

Dr. Michaelson states that [REDACTED]

[REDACTED]⁶⁰ [REDACTED] Experts, including Dr. Michaelson, are not permitted to speculate as to what "may" have occurred, or seek to offer causation opinions that are based on mere possibility. Dr. Michaelson is not only required to proffer his opinions to a reasonable degree of medical certainty, but also to opine that such opinions are

⁵⁸ Ex. 20, Bahnsen – Voelker Report, at 6 n.5; *see also*, Ex. 19 Bahnsen – Donnelly Report, at 8, n.7 (explaining that [REDACTED]).

⁵⁹ In the Fourth Circuit, a reliable methodology for a specific causation opinion could include, for example, a differential diagnosis. *See, e.g., Westberry v. Gislaved Gummi AB*, 178 F.3d at 262-63 (pointing out that "the overwhelming majority of the courts of appeals that have addressed the issue have held that a medical opinion based upon a reliable differential diagnosis is sufficiently valid to satisfy the first prong of the Rule 702 inquiry.") Not only did Dr. Michaelson [REDACTED]

[REDACTED]. Additionally, "[s]ome courts have held that... specific causation [can be] based on epidemiologic studies that find a relative risk of injury of 2.0 or higher and what is referred to as 'the logic of the effect of doubling of the risk.'" *In re Lipitor (Atorvastatin Calcium) Mktg.*, 150 F. Supp. 3d 644, 649 (D.S.C. 2015). Again, Dr. Michaelson does not use this methodology in proffering his specific causation opinion given that he plainly states [REDACTED]

[REDACTED]. *See* Ex. 3, Michaelson - Voelker Report, at 6; *see also*, Ex. 1, Michaelson - Donnelly Report, at 6; Ex. 2, Michaelson - Speers Report, at 6.

⁶⁰ Ex. 3, Michaelson - Voelker Report, at 3.

more likely than not true. “Speculative possibilities contained in this conclusion are not saved by the use of ‘reasonable degree of medical certainty’ language.” *Sharpe v. United States*, 230 F.R.D. 452, 461 (E.D. Va. 2005)(citing *Owens v. Bourns, Inc.*, 766 F.2d 145, 150 (4th Cir. 1985)). Because Dr. Michaelson’s opinion [REDACTED] [REDACTED] is entirely speculative, it should be precluded.

C. Dr. Raj Satkunasivam’s General Causation Opinion that [REDACTED] [REDACTED] is Unreliable and Inadmissible as He Failed to Follow a Proper Methodological Protocol for His Literature Review.

In addition to proffering a case-specific causation opinion, Dr. Satkunasivam also opines that [REDACTED].⁶¹ In reaching this opinion, Dr. Satkunasivam states that [REDACTED]⁶². However, there is no clear, reproducible method and/or reasoning that he followed in selecting his included literature and/or clear protocol for weighting the studies he ultimately discusses in his report.

First, Dr. Satkunasivam fails to [REDACTED] [REDACTED] thus making it impossible to understand why the [REDACTED] studies that he did include were ultimately included. Further, he notes that he [REDACTED]^{63, 64} [REDACTED]. He did not do a systematic review of the epidemiological literature, which, as discussed above, [REDACTED] is the appropriate methodology for reviewing and assessing epidemiological studies. Rather, Dr.

⁶¹ Ex. 4, Satkunasivam – Voelker Report, at 3.

⁶² Ex. 4, Satkunasivam – Voelker Report, at 12.

⁶³ Ex. 4, Satkunasivam – Voelker Report, at 12.

⁶⁴ Notably, Plaintiffs’ general causation expert [REDACTED]

Satkunasivam simply [REDACTED]

[REDACTED].⁶⁵ Without a proper review protocol, including identifiable weighting of the importance of the listed epidemiological studies, Dr. Satkunasivam's literature review is just a listing of studies included for the purpose of supporting a predetermined conclusion.⁶⁶

Moreover, although Dr. Satkunasivam discusses [REDACTED]

[REDACTED], including IARC, NASEM, and ATSDR, [REDACTED]

[REDACTED] EPA's 2024 conclusion that PFOA and PFOS are Likely to Be Carcinogenic to Humans [REDACTED]. Of course, this is entirely consistent with what seems to have been mere cherry-picking with regard to the scope of his literature review without any clear methodological protocol. *See Vieira v. Think Tank Logistics, LLC (In re Levesque)*, 653 B.R. 127, 140 (Bankr. D.S.C 2023)(stating that “[i]n order to be admissible, an expert opinion requires some explanation as to how the expert came to his conclusion and what methodologies or evidence substantiate that conclusion.”)

Further, failure to address evidence directly relevant to an experts' opinion, such as EPA's PFAS carcinogenicity conclusions, is also an independent basis for exclusion of his opinions. *See In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 341 F. Supp. at 242 (S.D.N.Y.

⁶⁵ Notably, [REDACTED], Dr. Satkunasivam appears to [REDACTED] Ex. 4, Satkunasivam – Voelker Report, at 25. Further, he fails to [REDACTED]

[REDACTED] *Id.* That is hardly a fulsome basis for an expert opinion.

⁶⁶ Defendants may argue that [REDACTED] However, any overlap in identified studies between experts does not do away with an expert's requirement under *Daubert* and Rule 702 to adhere to reliable reasoning and/or methodology when rendering expert opinions.

2018)(stating that “[w]here an expert ignores evidence that is highly relevant to his conclusion, contrary to his own stated methodology, exclusion of the expert’s testimony is warranted.”); *see also, Trevino v. Boston Sci. Corp.*, No. 13-cv-1617, 2016 U.S. Dist. LEXIS 65967, *23 (S.D.W.V. May 18, 2016)(stating that “[a]n expert’s opinion may be unreliable if he fails to account for contrary scientific literature and instead ‘selectively [chooses] his support from the scientific landscape.’”)(citing *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted); *In re Nellson Nutraceutical, Inc.*, 356 B.R. 364, 373 (Bankr. D. Del. 2006) (stating that “if the factual basis of an expert’s opinion is so fundamentally unsupported because the expert fully relies on . . . speculation, or fails to consider relevant facts in reaching a conclusion, the expert’s opinion can offer no assistance to the trier of fact, and is not admissible on relevance ground.”)

Finally, the entire basis for Dr. Satkunasivam’s [REDACTED]

[REDACTED] a publication by Drury et al.⁶⁷ Notably, this “publication” is actually a commentary that was co-authored by three individuals, two of whom have served as defense experts in PFAS litigation, including Dr. Barbara Beck, who was proffered by 3M as an expert in *Stuart v. 3M*, No. 18-cv-3487, which was pending in this MDL. While reliance on this report may not be methodologically inadequate on its own, [REDACTED]

further demonstrates Dr. Satkunasivam’s slipshod approach. In any case, [REDACTED]

Because Dr. Satkunasivam did not follow proper methodology or reasoning, he should be precluded from opining that [REDACTED].

⁶⁷ Ex. 4, Satkunasivam – Voelker Report, at 12.

D. Dr. David Braun's Opinion that [REDACTED] is Not Based on Reliable Reasoning and/or Methodology and is Therefore Inadmissible.

Dr. D. Braun states that [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

⁶⁸

While Dr. D. Braun described a [REDACTED] he failed to identify any well-established methodology to explain how he selected the medical literature he reviewed, failed to conduct a systematic review with well-established guidelines, failed to explain how he conducted his search of literature using PubMed, failed to identify inclusion or exclusion criteria for the studies he reviewed, and failed to identify the search criteria he used for his

⁶⁹

Instead, in support of his opinions that [REDACTED]
[REDACTED], Dr. D. Braun provides [REDACTED]
[REDACTED]⁷⁰—with no explanation as to how [REDACTED] was compiled, much less “rigorously explain” how he has “weighted the criteria” for compiling the list. *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 341 F. Supp. at 247; *see also, e.g., Magistrini*, 180 F. Supp. 2d at 602 (An expert must “weight[] the studies he has chosen to include in order to prevent a mere listing of studies and jumping to a conclusion.”).

⁶⁸ Ex. 7, D. Braun – *Donnelly Report*, at 16.

⁶⁹ Ex. 7, D. Braun – *Donnelly Report*, at 15-16.

⁷⁰ Ex. 7, D. Braun – *Donnelly Report*, at 16.

Furthermore, he opines that [REDACTED]

[REDACTED]

[REDACTED]”⁷¹ This opinion appears to be based solely on [REDACTED]. Further, he notes that [REDACTED]

[REDACTED],⁷² which, aside from being entirely irrelevant, is of course, entirely inconsistent with the Guidelines established by NASEM, which provide recommendations for screening when patients have known PFAS exposure. Given that Dr. D. Braun’s opinion is unsupported by any systematic research or data, it is unreliable under *Daubert* and the Federal Rules of Evidence and should be excluded.⁷³

E. Dr. Thomas Guzzo’s General Causation Opinion that [REDACTED] is Unreliable and Inadmissible as He Failed to Follow a Proper Methodological Protocol for His Literature Review.

Dr. Guzzo opines that [REDACTED]

[REDACTED]⁷⁴ In coming to this conclusion, Dr. Guzzo states that [REDACTED]

[REDACTED]

[REDACTED]⁷⁵ However, there is no clear, reproducible methodology and/or reasoning that

⁷¹ Ex. 7, D. Braun – *Donnelly* Report, at 24.

⁷² *Id.*

⁷³ Later in his report, he appears to temper that opinion, stating [REDACTED]

[REDACTED] Ex. 7, D. Braun – *Donnelly* Report, at 29.

⁷⁴ Ex. 5, Guzzo – *Speers* Report, at 17.

⁷⁵ Ex. 5, Guzzo – *Speers* Report, at 9.

he followed for weighting the studies he ultimately discusses in his report, and his omission of other relevant studies make his opinion unreliable.

First, like Dr. Satkunasivam, Dr. Guzzo fails to identify any search terms that he used for his literature review, thus making it impossible to understand why the [REDACTED] studies that he reviewed were included in his report. A proper methodology should include “identifying search terms likely to turn up relevant peer-reviewed studies, describing a grading system based on objective criteria, and walking through every step of” the process that the expert uses to reach their conclusion. *In re Abbott Lab’ys*, 2025 U.S. Dist. LEXIS 84032, at *116 (N.D. Ill. May 2, 2025). Dr. Guzzo utterly fails to meet this standard in his report.

Dr. Guzzo apparently cherry-picked studies to review because he fails to address, without any explanation, studies and conclusions that are clearly relevant to any expert’s opinion [REDACTED] [REDACTED], including EPA’s 2024 conclusion that PFOA and PFOS are Likely to Be Carcinogenic to Humans, IARC’s classification of PFOA as carcinogenic to humans (Group 1),⁷⁶ and NASEM’s finding that there was “sufficient evidence of increased risk...with exposure to PFAS”⁷⁷ and kidney cancer in adults. Indeed, Dr. Guzzo’s report [REDACTED]

[REDACTED] Dr. Guzzo’s failure to address studies and findings that do not support his seemingly preconceived opinion that [REDACTED]

[REDACTED] is a basis to exclude his opinion under *Daubert*. *Id.* at *18 (citation omitted); *see also, Daniels-Feasel v. Forest Pharms., Inc.*, No. 17-cv-4188, 2021 U.S. Dist. LEXIS 168292, at *13-14 (S.D.N.Y. 2021) (finding that “exclusion of

⁷⁶ 2025 IARC Monograph, at 717, available at: <https://publications.iarc.who.int/636>.

⁷⁷ NASEM Guidance, at 143-144, available at: <https://nap.nationalacademies.org/download/26156#>.

proffered testimony is warranted where the expert fails to address evidence that is highly relevant to his or her conclusions.”)

In short, Dr. Guzzo did not follow a proper methodology by failing to identify search terms, which makes it impossible to determine if he performed a proper systematic review of the relevant literature, by failing to properly identify and weigh the studies he reviewed, and by failing to consider studies and agency conclusions that do not support his opinion. His opinion, therefore, is unreliable, would mislead the jury, and should be excluded under *Daubert*.

F. Dr. Jennifer Gordetsky’s Opinion that [REDACTED]

[REDACTED] is Unreliable and Inadmissible.

Dr. Gordetsky’s opinion that [REDACTED]

[REDACTED], should be excluded because she fails to adhere to and/or identify a reliable methodology that she followed to come to such affirmative causation opinions. Moreover, the unreliability of her opinions in this case are underscored by her own concession that she [REDACTED]

[REDACTED].

1. Dr. Gordetsky’s [REDACTED] Includes No Methodology and/or Explanation of the Scope of the Literature Reviewed and/or Weight any Such Literature Was or Was Not Given.

In her report, Dr. Gordetsky purports to [REDACTED]⁷⁸ Following this review of the literature, Dr. Gordetsky opines that [REDACTED]

⁷⁸ Ex. 8, Gordetsky - *Voelker Report*, at 24; *see also*, Ex. 9, Gordetsky - *Donnelly Report*, at 24; and Ex. 10, Gordetsky - *Speers Report*, at 24.

[REDACTED]⁷⁹ She claims that this opinion is based on [REDACTED]

[REDACTED]"⁸⁰ (emphasis added)

Dr. Gordetsky should not be permitted to opine that [REDACTED]

[REDACTED] because she failed to identify and/or adhere to any well-established methodology to explain how she selected the literature that she reviewed to come to her conclusion that [REDACTED], nor did she explain what weight, if any, any particular piece of literature she reviewed was given. Because no methodology was followed for her literature review, but rather literature was cherry-picked for unexplained reasons without any analysis of the import of each specific piece of literature reviewed, Dr. Gordetsky's opinions are not reliable and, therefore, should be excluded.

Like her counterparts, Dr. Gordetsky also does not employ a systematic review methodology, she does not identify inclusion or exclusion criteria for the studies she reviewed, she does not identify the search criteria that she used to identify the universe of studies that she reviewed, nor does she assess the validity of studies through a bias assessment or interpret the epidemiological studies pursuant to any identified epidemiological protocols. Rather, her study selection likewise appears to be unreliable cherry-picking.

Although Dr. Gordetsky acknowledges that [REDACTED]

[REDACTED]

[REDACTED]

⁷⁹ Ex. 8, Gordetsky - *Voelker Report*, at 37-38; *see also*, Ex. 9, Gordetsky - *Donnelly Report*, at 36; and Ex. 10, Gordetsky - *Speers Report*, at 35.

⁸⁰ Ex. 8, Gordetsky - *Voelker Report*, at 4; *see also*, Ex. 9, Gordetsky - *Donnelly Report*, at 4; and Ex. 10, Gordetsky - *Speers Report*, at 4.

[REDACTED]⁸¹ she fails to explain why [REDACTED]

[REDACTED]. She provides no assessment as to why she reviewed this document, whether it met her search criteria, whether she did any bias assessment, and/or what conclusion she drew as to the overall quality of this evidence vis-à-vis any other specific literature she reviewed.

Similarly, Dr. Gordetsky states that [REDACTED]

[REDACTED]

[REDACTED]

⁸²

Again, she fails to explain why IARC's ultimate conclusion that PFOA is carcinogenic to humans should be rejected in favor of her opinion [REDACTED]. She does not explain why this monograph was included in her review, whether this monograph was evidence that she weighted highly or not vis-à-vis other literature she reviewed, and/or whether there was any bias and/or validation issues that may have limited the monograph's worth.

Shockingly, [REDACTED], using a systematic review, EPA concluded that PFOA was Likely to be Carcinogenic to Humans based on the fact that “[a]nimal toxicological studies in Sprague-Dawley rats reported Leydig cell tumors (LCT), pancreatic acinar cell tumors (PACT), and hepatocellular tumors after chronic oral exposure. Available mechanistic data suggest that multiple modes of action (MOAs) play a role in the renal, testicular, pancreatic, and hepatic tumorigenesis associated with PFOA exposure in humans and animal models.”⁸³ As

⁸¹ Ex. 8, Gordetsky - *Voelker* Report, at 25; *see also*, Ex. 9, Gordetsky - *Donnelly* Report, at 25; and Ex. 10, Gordetsky - *Speers* Report, at 25.

⁸² Ex. 8, Gordetsky – *Voelker* Report, at 26; *see also*, Ex. 9, Gordetsky - *Donnelly* Report, at 26; and Ex. 10, Gordetsky - *Speers* Report, at 26.

⁸³ EPA Final PFOA Toxicity Assessment, at xxiv, *available at*: <http://epa.gov/system/files/documents/2024-05/final-human-health-toxicity-assessment-pfoa.pdf>.

noted above, failure to include prime and relevant documents and/or literature to one's conclusion is alone a basis of exclusion. *See Daniels-Feasel*, 2021 U.S. Dist. LEXIS 168292, at *13-14. Of course, because Dr. Gordetsky [REDACTED]

[REDACTED] it is not possible to determine why EPA's conclusions were not included. Given that Dr. Gordetsky's causation opinions are [REDACTED]

[REDACTED], it is vital for any literature review she undertook to, at a minimum, explain why [REDACTED]
[REDACTED]
[REDACTED].

2. Dr. Gordetsky's Opinions Should Be Excluded Because She Failed to Use the Requisite Level of Scientific Rigor in Proffering her Opinions.

Finally, Dr. Gordetsky's opinions should be excluded because she failed to use the same level of scientific rigor in proffering her opinions that she uses in her field. Dr. Gordetsky [REDACTED]

[REDACTED].⁸⁴ In particular, Dr. Gordetsky states that [REDACTED]

[REDACTED]⁸⁵ She notes that the [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

,⁸⁶

⁸⁴ Ex. 8, Gordetsky - *Voelker* Report, at 2; Ex. 9, Gordetsky - *Donnelly* Report, at 2; and Ex. 10, Gordetsky - *Speers* Report, at 2.

⁸⁵ *Id.*

⁸⁶ *Id.*

Despite acknowledging that [REDACTED]

[REDACTED], Dr. Gordetsky concedes that [REDACTED]

[REDACTED].⁸⁷ In other words, Dr. Gordetsky failed to [REDACTED] t. Because Dr. Gordetsky did not have and did not [REDACTED]

[REDACTED], she failed to use the same level of rigor in this case as she purports to use in her field. This failure further underscores the unreliability of her methodology in reaching her opinion that [REDACTED]

[REDACTED]. Her opinions that [REDACTED]
[REDACTED]

[REDACTED] should be excluded for this reason as well.

G. Both Dr. Peter Clark's General and Specific Causation Opinions Should Be Excluded.

1. Dr. Clark's Opinion that [REDACTED]

[REDACTED] is Unreliable and Inadmissible.

Dr. Clark's opinion that [REDACTED]

[REDACTED], should be excluded because he fails to adhere to and/or identify any reliable methodology that he followed to come to such an opinion.

⁸⁷ Ex. 8, Gordetsky - *Voelker* Report, at 36; Ex. 9, Gordetsky - *Donnelly* Report, at 35; and Ex. 10, Gordetsky - *Speers* Report, at 34.

Dr. Clark should not be permitted to opine that [REDACTED]
[REDACTED], because similar to Defendants' other experts, he also failed to explain what weight, if any, a particular piece of literature he reviewed was given. Despite [REDACTED] a proper review of epidemiological literature provides for a systematic review of such literature, and despite Dr. Clark [REDACTED]
[REDACTED], Dr. Clark nonetheless does not employ a systematic review methodology. Dr. Clark also does not identify inclusion or exclusion criteria for the studies he reviews, [REDACTED]
[REDACTED], nor does he assess the validity of studies through a bias assessment or interpret the epidemiological studies pursuant to any identified epidemiological protocols. For example, Dr. Clark appears to [REDACTED]
[REDACTED]
[REDACTED], such as a study of a PFAS-exposed community in Australia or a Swedish study that showed an increased risk in one study group.⁸⁸ Dr. Clark's [REDACTED]
[REDACTED]
[REDACTED] underscores the fact that his opinion is based on favored cherry-picked documents and not a proper methodology.

2. Dr. Clark's Specific Causation Opinion that [REDACTED] is Not the Product of Reliable Reasoning and/or any Identifiable Methodology.

Dr. Clark's affirmative case-specific causation opinion that [REDACTED]
[REDACTED] is unreliable because Dr. Clark again fails to

⁸⁸ Ex. 11, Clark – *Donnelly Report*, at 5-6.

identify any methodology and/or reliable reasoning that he followed to arrive at his specific causation opinion, thereby rendering his specific causation opinion unreliable and inadmissible. In his report, Dr. Clark states that [REDACTED]

[REDACTED] ⁸⁹ Dr. Clark's specific causation opinion must be based on a reliable foundation and/or methodology, which it is not. In fact, no methodology is identified at all other than his self-serving claims, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED].⁹⁰ Dr. Clark also provides no rationale for why he opines that [REDACTED]

[REDACTED], which is rare for kidney cancer as most cases are in individuals between 55-74.⁹¹ As stated above, Dr. Clark [REDACTED]

[REDACTED] Dr. Clark provides no explanation for his conclusion that [REDACTED]
[REDACTED]. Dr. Clark cannot rule out one possibility while ruling in another remote possibility with no scientific explanation or support.

⁸⁹ Ex. 11, Clark – *Donnelly Report*, at 11.

⁹⁰ Ex. 11, Clark – *Donnelly Report*, at 12.

⁹¹ American Cancer Society Website, available at: <https://www.cancer.org/cancer/types/kidney-cancer/about/key-statistics.html#:~:text=The%20average%20age%20of%20people,Indian%2C%20and%20Alaska%20Native%20people> (noting that kidney cancer is rare in people under 45 and most common between the ages of 55-74).

H. Drs. Brian Rini's and Michael Palese's Opinions that [REDACTED] are Unreliable and Inadmissible.

Both Drs. Rini and Palese opine that [REDACTED]

[REDACTED]

[REDACTED] These opinions should likewise be excluded because they fail to identify any reliable methodology that was followed to come to such an affirmative causation opinion.

These purported experts should not be permitted to opine that [REDACTED]

[REDACTED] because they failed to explain the methodology by which they evaluated the literature they purport to have reviewed. Absent a disclosure of their methodology, Plaintiffs and the Court are left to guess at what, if any, methodology was employed.

See Magistrini, 180 F. Supp. 2d 584. Dr. Rini states in a conclusory manner that [REDACTED]

[REDACTED].⁹² Thereafter, Dr. Rini [REDACTED]
[REDACTED]
[REDACTED]. Worse yet, Dr. Palese states that [REDACTED]
[REDACTED]
[REDACTED].⁹³ [REDACTED].

Then, just like all the other challenged experts, [REDACTED]
[REDACTED]. As both Drs. Rini and Palese use their unreliable and inadmissible conclusions that [REDACTED]
[REDACTED]

⁹² Ex. 13, Rini – *Voelker Report*, at 6.

⁹³ Ex. 12, Palese – *Speers Report*, at 13.

[REDACTED], their case-specific causation opinions are likewise unreliable and inadmissible.⁹⁴

I. Dr. Martin Ronis' General Causation Opinions Are Unreliable and Inadmissible as He Failed to Follow a Proper Methodological Protocol for His Literature Review.

Dr. Ronis, a biological toxicologist, opines generally that [REDACTED]

[REDACTED]. He also disputes the notion that [REDACTED]

[REDACTED]. In reaching these opinions, Dr. Ronis states that [REDACTED]

[REDACTED]”⁹⁵ This statement represents the only methodology described by Dr. Ronis. While he cites [REDACTED] in his reference list, he provides no criteria for how he determined which studies to reference or consider. Accordingly, he

⁹⁴ “Expert reports must not be sketchy, vague or preliminary in nature. Expert reports must include the ‘how’ and ‘why’ the expert reached a particular result, not merely the expert’s conclusory opinions.” *Atlantic Coast Pipeline, LLC v. 0.07 Acre, More or Less*, 396 F.Supp.3d 628, 636 (W.D. Va. 2019). “Every litigant in federal court is plainly entitled under Rule 26(a)(2)(B) to be given information spelled out therein, and none shoulder the burden to independently investigate and ferret out that information as best they can and at the expense of their client.” *Carr v. Deeds*, 453 F.3d 593, 605 (4th Cir. 2006). In *Campbell v. United States*, 470 Fed. Appx. 153, 156 (4th Cir. 2012), the Fourth Circuit affirmed the exclusion of plaintiff’s expert because he failed to delineate or explain the factual basis for his conclusions. Accordingly, courts within the Fourth Circuit rigorously enforce the requirements of Rule 26 disclosures to exclude expert reports that fail to adequately disclose the experts’ methodology, *i.e.*, the basis and reasons for their opinion. *See, e.g., Hulsey v. HomeTeam Pets Defense LLC*, No. 2:10-cv-03265, 2012 WL 2366385 (D.S.C. June 21, 2012) (excluding report that “utterly fails to comply with the dictates of Federal Rule of Civil Procedure 26(a)(2)(B). *** “to admit an expert report with this level of noncompliance with Rule 26(a) would set a very low bar for admissibility of reports going forward.”).

⁹⁵ Ex. 14, Ronis Report, at 3.

has not met the standard for establishing that he followed clear methodology and reasoning in determining which studies to consider and discuss in his report.

Like many of Defendants' experts discussed above, Dr. Ronis fails to identify any search terms that he used for his literature review, thus making it impossible to understand why the studies that he reviewed were included in his report. A proper methodology should include "identifying search terms likely to turn up relevant peer-reviewed studies, describing a grading system based on objective criteria, and walking through every step of" the process that the expert uses to reach their conclusion. *In re Abbott Lab'ys*, 22-C-00071, 2025 U.S. Dist. LEXIS 84032, at *116 (N.D. Ill. May 2, 2025). Dr. Ronis fails to do this. Accordingly, to the extent he is offering an affirmative opinion that [REDACTED]

[REDACTED], such opinion should be excluded for lack of a proper and reproducible methodology.

Dr. Ronis' opinions [REDACTED] fair no better.

⁹⁶ Expert Report of Dr. David H. Sherman, Ph.D., dated February 17, 2025 (“Sherman Report”), at 26, attached hereto as Ex. 24.

[REDACTED]

[REDACTED]

[REDACTED] .⁹⁷

While Dr. Ronis [REDACTED]
[REDACTED]. For example, Dr. Sherman explains that [REDACTED]
[REDACTED]
[REDACTED].⁹⁸ In response, Dr. Ronis acknowledges [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED].⁹⁹ He does not explain why he credits or provides greater weight to [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].¹⁰⁰ While Dr. Ronis *may* have some basis to [REDACTED], he has failed to

⁹⁷ *Id.* at 27.

⁹⁸ *Id.* at 30.

⁹⁹ Ex. 14, Ronis Report, at 15.

¹⁰⁰ On this dose point, Dr. Sherman further explained at his deposition:

[REDACTED]

provide it. This abject failure renders his opinions essentially useless and unreliable. Absent such an explanation, he has failed to demonstrate a reliable methodology which would allow the Court or a Jury to credit his opinions [REDACTED] as anything more than mere assertion and speculation. While certainly everyone is entitled to an opinion, in a court of evidence one must provide the *basis* for one's opinion and Dr. Ronis has failed to do so.

Because Dr. Ronis failed to conduct a proper methodology by explaining how he conducted his research or why he gave greater weight to certain studies over others, his opinions are unreliable and should be excluded under *Daubert*. This is in direct contrast to Plaintiffs' expert, Dr. Sherman, who gave explicit details on how he weighed each of the pertinent studies to reach his conclusion that [REDACTED].¹⁰¹

[REDACTED]

Dep. Tr. of David H. Sherman, PhD, dated May 13, 2025 ("Sherman Dep."), at 101:12- 103:21, all relevant pages cited herein attached hereto as Ex. 18.

¹⁰¹ As further articulated at his deposition, Dr. Sherman explained:

[REDACTED]

Id. at 115:10-116:13.

J. Dr. Sarah Cohen Should Not Be Permitted to Opine that [REDACTED]
 or that [REDACTED]
 Because She Conceded that [REDACTED]
 and Because, by Her Own Admission, [REDACTED].

As set forth above, Dr. Cohen [REDACTED]

[REDACTED]¹⁰² In her expert report, she states that [REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED] ..¹⁰³

In her deposition, she made clear that her answer to this research question is that, in her opinion,
 [REDACTED]
 [REDACTED]¹⁰⁴ (emphasis added). Stated differently, she [REDACTED]
 [REDACTED]
 ..¹⁰⁵ (emphasis added). In other words, [REDACTED]
 [REDACTED]
 [REDACTED]. Given that Dr.
 Cohen [REDACTED]
 [REDACTED]
 [REDACTED], she should not be permitted to misleadingly opine that [REDACTED]
 [REDACTED].

¹⁰² *Supra*, at 12.

¹⁰³ Ex. 6, Cohen Report, at 3.

¹⁰⁴ Ex. 23, Cohen Dep., at 23:11-15.

¹⁰⁵ *Id.* at 23:18-21.

Dr. Cohen's failure to [REDACTED] is not surprising. This is because, as she conceded at her deposition, [REDACTED]

[REDACTED]

[REDACTED]. Specifically, when queried, she testified:

[REDACTED]
[REDACTED]
[REDACTED] 106

This is the proverbial ‘head in the sand’ approach, which is made all the worse by virtue of the fact that Dr. Cohen testified that [REDACTED], and thus presumably was well aware of the significance and importance placed on animal and mechanistic data in assessing the carcinogenicity of PFOA, which IARC classifies as “sufficient,” and “strong,” respectively.¹⁰⁷ Given the importance of these evidence streams, [REDACTED]

[REDACTED] is a death knell to her being permitted to opine as to [REDACTED]

[REDACTED] *See Daniels-Feasel v. Forest Pharms., Inc.*, No. 17-cv-4188, 2021 U.S. Dist. LEXIS 168292, at *13-14 (S.D.N.Y. 2021) (finding that “exclusion of proffered testimony is warranted where the expert fails to address evidence that is highly relevant to his or her conclusions.”); *see also, supra*, at 21-22 for additional supporting citations.

In light of the foregoing, Dr. Cohen should not be permitted to testify that [REDACTED]

[REDACTED]

[REDACTED] Finally, to the extent that any of the other dozens of defense experts

¹⁰⁶ *Id.* at 162:12-18; *see also, id.*, at 21:7-22:4 (testifying that [REDACTED]).

¹⁰⁷ 2025 IARC Monograph, at 717.

[REDACTED], they too

should be precluded from offering any similarly misleading opinions.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs' motion should be granted and the experts' opinions challenged herein excluded from trial.

Dated: June 17, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was electronically filed with this Court's CM/ECF on this 17th day of June 2025 and was thus served electronically upon counsel of record.

/s/ Fred Thompson, III
Fred Thompson